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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/675,225

09/29/2003

Kameron W. Maxwell

MITOS.002A

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7590

04/11/2006

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/675,225

Applicant(s)

MAXWELL ET AL.

Examiner

James W. Rogers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09/29/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 08/09/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6-10, 12-18, 20-25 are rejected under 35 U.S.C. 102(b) as being unpatentable by Mitchell et al. (US 5,462,946).

Mitchell teaches pharmaceutical compositions and their methods of use, the compositions contain nitroxide compounds (including TEMPOL) that can be used as radiation protectants for skin, mucositis and hair loss (also known as alopecia), which can be applied as an ointment, lotion or cream (satisfying the claim for a gel or thickened liquid), and intravenously or orally by pill or lozenge. See col 1 lin 10-13, col 2 lin 53-58 and claims 1 and 10. While the patent is silent on specific solvents it is deemed inherent by the examiner that in order to make a topical cream or lotion the active ingredient would have to be dissolved in some type of solvent and the patent describes the compounds having concentrations of from 1-5 mM and the use of acceptable carriers. See col 4 lin 40-42 and lin 47-51. Regarding claims 7 and 21, while Mitchell only discloses treatment of skin conditions, it is inherent that protecting against skin conditions commonly associated with radiotherapy would include group in claims 7 and 21 (discussed as being common skin conditions in applicants spec [0004]) and since the radioprotective agent is the same in both patents it would protect against

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all skin conditions the same as applicants claimed invention. Regarding claim 10, the Mitchell patent teaches the exact same amount of active ingredient for topical use as the applicant. See col 5 lin 18-21. Regarding claims 12 and 25, it is deemed inherent by the examiner and a normal part of experimentation by someone skilled in the art to adjust the viscosity of a topical gel so that it "will remain in contact with a treated area for a sufficient period of time to allow absorption of a pharmacologically effective amount into said treated area" thus this claim was given no patentable weight by the examiner. Regarding claims 24 and 25, applying the composition topically to prevent harmful effects of radiotherapy is taught by Mitchell (see col 2 lin 53-58) and evaporating solvent after applying topically is inherent since the solvents listed are volatile (methanol) and would eventually evaporate when applied to a persons skin.

Claims 1-9 and 11-25 are rejected under 35 U.S.C. 102(b) as being unpatentable by Golz-Berner et al. (US 6,426,080 B1 is used as an English equivalent to WO 99/66881).

Golz-Berner teaches a cosmetic preparation of active substances to protect the skin (including TEMPOL) in the form of a gel composed of hydrogels (including natural polymers such as hydroxymethylcellulose), solvent (including ethanol) and other ingredients such as carriers (propylene glycol and water are listed). See col 3 lin 23-29 col 6 lin 6-9, col 7 lin 3 and lin 60-62, col 9 lin 13 and lin 37-40. The examiner gave no patentable weight to the intended use phrase in claim 1 "for use in ameliorating an effect of radiotherapy on the skin, ect" because this is only an intended use and therefore has no patentable weight on the pharmaceutical composition. The examiner

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gave no patentable weight to the treatment of the various skin, hair and mucous membrane conditions since the radioprotective agent (TEMPOL) is the same in both patents, it is inherent that since the claimed ingredient and the ingredient in the Golz-Berner patent are the same it would have the same effect against radiotherapy.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (US 5,462,946) in view of Golz-Berner et al. (US 6,426,080 B1 is used as an English equivalent to WO 99/66881).

The Mitchell patent teaches as above.

The Mitchell patent is silent on the exact solvents and polymers used in the topical skin application.

The Golz-Berner patent teaches as above.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Mitchell discloses all of the claimed invention by the applicants except the exact solvents and polymers used while Golz-Berner discloses a cosmetic preparation of active substances to protect the skin including TEMPOL and discloses the use of solvents, carriers and hydrogels which are the same as the applicants claimed ingredients (ethanol, propylene glycol, water and natural polymers). The motivation to combine the two documents would be the formulation of a pharmaceutical topical gel for use as a radioprotector, the gel composition comprised of TEMPOL, solvent and polymers.

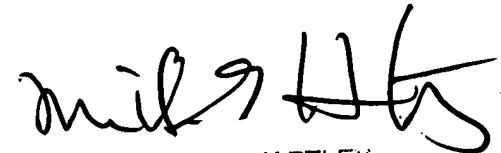
### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER